Miltex
Redefining Excellence

DEC 2 9 2009

K092855

589 Davies Drive
York, PA 17402
phone 717 840-9335
toll-free 800 221-1344
fax 717 840-9347
www.miltex.com

510(k) Summary

Submitted by: Miltex, Inc.
589 Davies Drive
York, PA 17402 USA

Contact Person: Jennifer Bosley, Regulatory Affairs Manager
Integra Medical Instrument Group
589 Davies Drive
York, PA 17402 USA
Phone: (717) 840-9335
Fax: (717) 840-3509

Date Prepared: September 15, 2009

Device Trade Name: Miltex® Membrane Tack Kit
Common/Usual Name: Dental Membrane Tack
Proposed Classification: Screw, Fixation, Intraosseous
21 CFR 872.4880 Class II, 76 DZL – Dental

Device Description:
The Miltex® Membrane Tack Kit consists of non-sterile, single use titanium alloy tacks available in 3 mm or 5 mm lengths. Membrane Tacks are used in conjunction with the following accessories and reusable stainless steel instruments for implantation: Tack Membrane Probe, Tack Applicator, Perforation Raspatory, Kirsch Sinus 7 Double-ended Spoon and Plugger, Sinus Elevator, Mixing Cup with Plastic Lid, Tack Storage Box for 15 Tacks and Tack Wash Tray with Lid.

Indications For Use:
Miltex® Membrane Tack Kit is intended to fixate or stabilize guided tissue regeneration membranes to bone at the surgical site.

Predicate Devices:

510(k) #	Device	Manufacturer
K973180	IMTEC Bone Tac	IMTEC Corporation
K022790	AutoTac™ System Titanium Tack	BioHorizons Implant Systems, Inc.

Substantial Equivalence:
Miltex® Membrane Tack Kit is substantially equivalent to the legally marketed predicate devices with respect to intended use, fundamental technology, design and material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Ms. Jennifer Bosley
Regulatory Affairs Manager
Miltex, Incorporated
Integra Medical Instrument Group
589 Davies Drive
York, Pennsylvania 17402

DEC 2 9 2009

Re: K092855
Trade/Device Name: Miltex® Membrane Tack Kit
Regulation Number: 21CFR 872.4880
Regulation Name: Intraosseous Fixation Screw or Wire
Regulatory Class: II
Product Code: DZL
Dated: December 16, 2009
Received: December 17, 2009

Dear Ms. Bosley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 of 1

K092855

Indications For Use

510(k) Number (if known): _____

Device Name: Miltex® Membrane Tack Kit

Indications for Use:

Miltex® Membrane Tack Kit is intended to fixate or stabilize guided tissue regeneration membranes to bone at the surgical site.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter-Use _____ (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092855